NATIONAL MARROW DONOR PROGRAM®

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April 29, 2013

LCDR Christopher Steele
Office of Naval Research
Code 34 – Warfighter Performance
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-12-1-0142 between the Office of Naval Research and the National Marrow Donor Program

Dear LCDR. Steele:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of January 1, 2013 to March 31, 2013.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention at 612-362-3403 or at cabler@nmdp.org.

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Contracts Manager

Enclosure: Quarterly Report with SF298

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-12-1-0142

DEVELOPMENT OF MEDICAL TECHNOLOGY FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY PERFORMANCE / TECHNICAL REPORT

FOR

JANUARY 01, 2013 to MARCH 31, 2013

PERIOD 5

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
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QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

January 01, 2013 through March 31, 2013

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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
IIA.1 Task 1: Secure Interest of Transplant Physicians	**Period 5 Activity:** • Continued coordination for an Advanced Medical Response to a Radiological Disasters training session at the Radiation Emergency Assistance Center and Training Site in Oakridge, TN to be held in May 2013 • Began coordination and planning for a mobile training version of the Advanced Medical Response to a Radiological Disasters; this mobile version will allow up to 100 people to be trained on the same material as the version held at the Radiation Emergency Assistance Center and Training Site in Oakridge, TN. This mobile session will be held at Duke University in August.
IIA.1 Task 2: GCSF in Radiation Exposure	**Period 5 Activity:** • No Activity
IIA.1 Task 3: Patient Assessment Guidelines and System Enhancements	**Period 5 Activity:** • No Activity
IIA 1 Task 4: National Data Collection Model – This task is closed.	
IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2 Task 1: Contingency Response Network	**Period 5 Activity:** • Continued to develop and release web based training modules for RITN, the following courses are released in use by RITN staff and RITN partners: o Introduction to RITN o Government Emergency Telecommunications Service (GETS) for RITN o Satellite Phone Training for RITN

- Basic Radiation Training (BRT)
- These two final courses are in the final stages of development with release anticipated for early summer 2013:
  - RITN Concept of Operations
  - Non-Medical Radiation Awareness Training

- Continued coordination of the Centers for Medical Counter Measures against Radiation (NIAID-CMCR) and RITN conference in Baltimore July 31-Aug 2;
  - The conference purpose and scope are:
    - The tremendous environmental, social, and medical cost of a large-scale release of nuclear or radiological material as a result of deliberate attack or natural disaster has led to several programs aimed at improving national and local preparedness.
    - The Radiation Injury Treatment Network (RITN) and the Centers for Medical Countermeasures against Radiation (CMCR) are convening a three-day workshop on the Mitigation and Treatment of Radiation Damage from July 31st to August 2nd, 2013 that will cover topics such as patient assessment, biomarkers and biodosimetry, suitability of animal models, small molecules, growth factors, and cells as mitigators, as well as their mechanisms of action in radiation-damaged tissues, late effects of acute and prolonged exposure, survivorship issues, and future developments. The workshop will be held at the historic Tremont Plaza Hotel.
    - The meeting will provide an open forum for invited and plenary speakers and discussants to assess progress on issues related to radiation injury, mitigation and treatment. Various radiation scenarios will be presented along with novel approaches at multiple stages of development.
  - The agenda will include:
    - Keynote Address: Preparedness and Response to Radiation
    - Possible Radiological Incident Scenarios

	▪ Casualty Triage and Distribution ▪ The RITN Response to Radiological Scenarios ▪ Emergency Management from the CMCR perspective ▪ Workshop 1: Biodosimetry and Biomarkers - assessing the need ▪ Animal Models of Radiation Damage and Confounders ▪ The Challenge underlying Radiation Mitigation ▪ Workshop 2: Small Molecule Radiation Mitigators ▪ Workshop 3: Growth Factors and Cytokines as Mitigators ▪ Workshop 4: Cell Replacement Approaches for Radiation Mitigation ▪ Workshop 5: Mitigation and Treatment of Late Effects ▪ Identification of the Grand Challenges in Radiation Mitigation and Treatment
IIA.2 Task 2: Sibling Typing Standard Operating Procedures	**Period 5 Activity:** • No activity this period.
IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3 Task 1: I.S. Disaster Recovery – This task is closed.	
IIA.3 Task 2: Critical Facility and Staff Related Functions	**Period 5 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
IIB.1 Task 1: Increase Registry Diversity	**Period 5 Activity:** • No activity this period.

IIB.1 Task 2: Evaluate HLA-DRB1 High Res typing – This task is closed.	
IIB.1 Task 3: Evaluate HLA-C Typing of Donors – This task is closed	
IIB.1 Task 4: Evaluate Buccal Swabs	**Period 5 Activity:** Buccal Swab Stability Study: In the current period, a working group began study design to assess the stability of Frozen Buccal Swab samples. In the next period, a baseline timepoint will compare swabs stored at room temperature, -30ºC, and -80ºC for quality of DNA, quantity of DNA, and high resolution HLA characterization.
IIB 1 Task 5: Enhancing HLA Data for Selected Donors – This task is closed.	
IIB 1 Task 6: Maintain a Quality Control Program	**Period 5 Activity:** During this quarter, 14 additional cell lines were received from the cell processing laboratory and incorporated into the regular QC rotation, bringing the total number of B-LCL QC Master lots obtained to date from this grant to 34. Of the 94 cells lines selected for incorporation into the QC program in FY2012, 50 have exhibited negative cell growth (47% cell culture success rate). Of the remaining 10 cell lines in progress, only 4 are progressing well; 6 are progressing slowly. To compensate for the poor culture success rate of the B-LCL lines, 26 replacement cells were shipped. B-LCL swabs are expensive and time consuming to prepare. In an effort to decrease the cost and increase the sustainability of the QC program, alternate sources of material that would yield more cost-effective types of QC swab samples are being investigated. One of these alternate types is purified genomic DNA absorbed onto cotton-tipped swabs ("DNA-swabs"). This alternative QC sample type has the potential to expand allelic coverage and diversity of HLA in the QC program by utilizing stored NMDP volunteer QC donor blood and Registry donors with desirable HLA types. In this quarter, 10 fully HLA-characterized NMDP volunteer QC donors were identified for inclusion in a pilot study to assess the feasibility of using purified DNA as an alternative QC sample type. DNA was extracted from stored frozen blood aliquots, and quantitative and qualitative analysis was performed. Frozen whole blood, swabs created from freshly extracted DNA, and real buccal swabs from the 10 volunteer NMDP QC donors was subsequently sent for testing to one lab. The swabs were HLA typed in an identical manner to the current HLA Typing of Registry Donors Agreement. In addition, the extracted DNA was evaluated for quantity and quality. Results are expected in the next quarter.

IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB 2 Task 1: Collection of Primary Data	**Period 5 Activity:** • No activity this period.
IIB 2 Task 2: Validation of Logic of Primary Data – This task is closed.	
IIB 2 Task 3: Reinterpretation of Primary Data – This task is closed.	
IIB 2 Task 4: Genotype Lists & Matching Algorithm	**Period 5 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3 Task 1: Phase I of EM Haplotype Logic	**Period 5 Activity:** The CME online program Screening and Preventive Practices for Survivors after Hematopoietic Cell Transplantation with Medscape Oncology was launched last quarter. The results to date have exceeded expectations. The last Medscape program, which was on Non Hodgkin's Lymphoma ended in July 2012 with a total of 6,500 learners. The current program has only been in existence for four months and already has over 8,000 learners representing an increase of 23%. This includes more than 1,600 US physicians. Results indicate very high impact with 93% of hematologists/oncologists indicating a change in practice based on this activity.
IIB 3 Task 2: Enhancement of EM Algorithm	**Period 5 Activity:** • No activity this period.
IIB 3 Task 3: Optimal Registry Size Analysis	**Period 5 Activity:** • IMMPUTE project o UCSF has compiled IRB approval and IRB waiver for this project. Incoming Material and data Transfer Agreements (MTAs) have been negotiated and signed between UCSF and

	CHORI. Similarly Outgoing MTAs have been set up with the participating institutions. As of April 2013, 3/5 MTAs have been successfully negotiated and signed. o The raw HLA data have been cleaned and formatted by CHORI in coordination with UCSF and NMDP groups, so that no assumptions-based re-formatting operations are required from the participants. o Finalized the processing of SNP data for the distribution to the external collaborators o Finalized the ambiguity reduction in HLA data for the distribution to the external collaborators o Designed and wrote an experimental plan to be distributed to the external collaborators which insures that all participating groups follow the same experimental set-up in order for the results to be comparable in the evaluation process.
IIB 3 Task 4: Target Under- Repre-sented Phenotypes	**Period 5 Activity:** • No activity this period.
IIB 3 Task 5: Bioinformatics Web Site	**Period 5 Activity:** • Designed, illustrated, and developed multimedia content for ongoing Bioinformatics projects: o Conducted research to develop content for "What is HLA" video and storyboard for "What is HLA" video o Made production changes to format of "Genetic Ancestry" video for Learning Modules
IIB 3 Task 6: Consultants to Improve Algorithm	**Period 5 Activity:** • Continued development to optimize the performance of the HapLogic algorithm
IIB 3 Task 7: Population Genetics – This task is closed.	
IIB 3 Task 8: Haplotype Matching – This task is closed.	
IIB 3 Task 9: Global Haplotype/Benchmark – This task is closed.	

IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

IIB.4 Task 1: Expand Network Communications – This task is closed.

IIB.4 Task 2: Central Contingency Management	**Period 5 Activity:** **AFA Few 10/10 Matched Donor Study** AFA patients represent an underserved population of patients seeking an unrelated stem cell transplant in the NMDP Registry. Increased HLA diversity, relatively low AFA donor representation on the registry, compounded with low AFA donor availability results in challenging searches for AFA patients. A research study was initiated to evaluate NMDP process interventions for AFA searches, which included proactive HLA expert review of AFA patient searches, proactive donor contact to confirm interest and availability, and proactive donor HLA typing upgrades. This study will examine whether clearly identifying matches for TCs with AFA patients can decrease the time and increase the likelihood of AFA patients making it to search formalization and transplant. This randomized group will be compared to AFA patients who follow the typical path through the NMDP where pre-search donor contact occurs under a computer selection algorithm, and search strategy advice and donor HLA typing are performed upon TC request. This project will be instrumental in understanding the ability for process changes to increase AFA patients getting to transplant, particularly in time of a contingency event. This period 62 patients entered the project, 754 donors had contact attempted on behalf of those patients, and 131 donors had HLA typing performed. **Abstract Presentations** **CD43+ yield correlates with donor age and sex** • An oral abstract was presented at the 2013 BMT Tandem Meeting. This study showed that younger donor age resulted in an increased likelihood of meeting the transplant physician's requested TNC or CD34+ dose. Lower donor age also was associated with increased CD34+ cell dose from PBSC collections, but not the TNC/kg obtained from marrow collections. In addition, male donors provided increased CD34+ cells/kg donor weight than female donors. Transplant center practice is often to select young male donors for patients, and this data provides evidence to support that such

	practice may increase the likelihood of a providing a product meeting a center's request. o John Hermanson, et al., *Young male donors provide the best chance of meeting requested cell dose for PBSC and bone marrow transplantation.* Oral presentation at the 2013 BMT Tandem Meetings. BBMT Supplemental Oral abstract 16. Feb 2013. **Selection of high TNC CBUs for pediatric patients** • A poster abstract was presented at the 2013 BMT Tandem Meeting. This study showed that CBU used in transplant for children can exceed 20 x 10^7 TNC/kg. These CBU have a large TNC and could be suitable for adolescent or adult single cord transplantation. Although 74 CBU transplants correspond to a small proportion of total pediatric (age 12 and under) single CBU transplant during this timeframe (n=951), these units may offer the only opportunity for an adult patient. With a limited number of CBUs achieving high TNC available for adult patients, consideration of the ethics of providing a young patient with an adequate TNC CBU (e.g. 10-20 x 10^7 TNC/kg) vs the largest TNC CBU will continue to confront the community. o Jason Dehn, et al., *How Much is Enough? Ethical Consideration for the Depletion of Large Public Cord Blood Units.* Poster presentation at the 2013 BMT Tandem Meetings. BBMT Supplemental Poster abstract S285. Feb 2013.
IIB.4 Task 3: Benchmarking Analysis – This task is closed.	
IIB.4 Task 4: Expand Capabilities of Collection and Apheresis Centers – This task is closed.	
IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
IIC.1 Task 1: Donor Recipient Pair Project	**Period 5 Activity:** • No activity this period.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
IIC 2 Task 1: Analysis of non-HLA loci	**Period 5 Activity:** • Developed export functionality in IPR (Immunobiology Project Results) database • Incorporated HapLogic matching service into clinical outcomes Immunobiology database.
IIC 2 Task 2: Related Pairs Research Repository – This task is closed.	
IIC 2 Task 3: CIBMTR Integration – This task is closed.	
IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1 Task 1: Observational Research, Clinical Trials and NIH Transplant Center	**Period 5 Activity:** • Activities during this quarter included completion of site monitoring related to the Adult Double Cord trial and continued data cleaning in preparation for manuscript development. • Staff from the RCI BMT continued to work with CIT staff to explore options for a) comprehensive system for management of activities and studies within the SRG and b) clinical trial management system (CTMS) to coordinate operational and administrative activities within RCI BMT. Responses from potential vendors have been received, scored and demos are being coordinated.
IID.1 Task 2: Research with NMDP Donors – This task is closed.	
IID.1 Task 3: Expand Immuno-biology Research	**Period 5 Activity:** • No activity this period.

ACRONYM LIST

AABB	American Association of Blood Banks	HR	High Resolution
AFA	African American	HRSA	Health Resources and Services Administration
AGNIS	A Growable Network Information System	HSC	Hematopoietic Stem Cell
AML	Acute Myelogenous Leukemia	IBWC	Immunobiology Working Committee
ABD	Antigen Binding Domain	IDM	Infectious Disease Markers
API	Asian Pacific Islander	IHWG	International Histocompatibility Working Group
AQP	Ancestry Questionnaire Project		
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IPR	Immunobiology Project Results
ASBMT	American Society for Blood and Marrow Transplantation	ICRHER	International Consortium for Research on Health Effects of Radiation
ASHI	American Society for Histocompatibility and Immunogenetics	IND	Investigational New Drug
ASTHO	Association of State and Territorial Health Officials	IS	Information Services
B-LCLs	B-Lymphoblastoid Cell Lines	IT	Information Technology
BARDA	Biomedical Advanced Research and Development Authority	IRB	Institutional Review Board
BBMT	Biology of Blood and Marrow Transplant	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BCP	Business Continuity Plan	KIR	Killer Immunoglobulin-like Receptor
BCPeX	Business Continuity Plan Exercise	MDACC	MD Anderson Cancer Center
BMCC	Bone Marrow Coordinating Center	MDS	Myelodysplastic Syndrome
BMDW	Bone Marrow Donors Worldwide	MHC	Major Histocompatibility Complex
BMT	Bone Marrow Transplantation	MICA	MHC Class I-Like Molecule, Chain A
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICB	MHC Class I-Like Molecule, Chain B
BODI	Business Objects Data Integrator	MKE	Milwaukee
BRT	Basic Radiation Training	MRD	Minimal Residual Disease
C&A	Certification and Accreditation	MSKCC	Memorial Sloan-Kettering Cancer Center

CAU	Caucasian	MSP	Minneapolis
CBMTG	Canadian Blood and Marrow Transplant Group	MUD	Matched Unrelated Donor
CBB	Cord Blood Bank	NAC	Nuclear Accident Committee
CBC	Congressional Black Caucus	NCBI	National Center for Biotechnology Information
CBS	Canadian Blood Service	NCBM	National Conference of Black Mayors
CBU	Cord Blood Unit	NACCHO	National Association of County & City Health Officials
CDA	Clinical Document Architecture	NARR	National Alliance for Radiation Readiness
CFU	Colony Forming Unit	NCI	National Cancer Institute
CHORI	Children's Hospital of Ockland Research Institute	NDMS	National Disaster Medical System
CHTC	Certified Hematopoeitic Transplant Coordinator	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CIBMTR	Center for International Blood & Marrow Transplant Research	NGS	Next Generation Sequencing
CIT	CIBMTR Information Technology	NHLBI	National Heart Lung and Blood Institute
CLIA	Clinical Laboratory Improvement Amendment	NIH	National Institutes of Health
CMCR	Centers for Medical Countermeasures against Radiation	NIMA	Non-Inherited Maternal Antigen
CME	Continuing Medical Education	NIMS	National Incident Management System
CMF	Community Matching Funds	NK	Natural Killer
CMV	Cytomegalovirus	NLE	National Level Exercise
COG	Children's Oncology Group	NMDP	National Marrow Donor Program
CREG	Cross Reactive Groups	NRP	National Response Plan
CSS	Center Support Services	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CT	Confirmatory Testing	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CTA	Clinical Trial Application	OIT	Office of Information Technology
DC	Donor Center	OMB	Office of Management and Budget
DHHS-ASPR	Department of Health and Human Service –	ONR	Office of Naval Research

	Assistant Secretary Preparedness and Response		
DIY	Do it yourself	P2P	Peer-to-Peer
DKMS	Deutsche Knochenmarkspenderdatei	PBMC	Peripheral Blood Mononuclear Cells
DMSO	Dimethylsulphoxide	PBSC	Peripheral Blood Stem Cell
DoD	Department of Defense	PCR	Polymerase Chain Reaction
DHHS-ASPR	Department of Health and Human Services – Assistant Secretary for Preparedness and Response	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
DR	Disaster Recovery	RCC	Renal Cell Carcinoma
D/R	Donor/Recipient	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DSTU	Draft Standard for Trial Use	REAC/TS	Radiation Emergency Assistance Center/Training Site
EBMT	European Group for Blood and Marrow Transplantation	REST	Representational State Transfer
ED	Emergency Department	RFP	Request for Proposal
EDC	Electronic Data Capture	RFQ	Request for Quotation
EFI	European Federation of Immunogenetics	RG	Recruitment Group
EM	Expectation Maximization	RITN	Radiation Injury Treatment Network
EMDIS	European Marrow Donor Information System	SBT	Sequence Based Typing
ENS	Emergency Notification System	SCTOD	Stem Cell Therapeutics Outcome Database
ERSI	Environment Remote Sensing Institute	SG	Sample Group
FBI	Federal Bureau of Investigation	SHF	Synthetic Haplotype Frequency
FDA	Food and Drug Administration	SLCBB	St. Louis Cord Blood Bank
		SLW	STAR Link® Web
FDR	Fund Drive Request	SSA	Search Strategy Advice
FLOCK	Flow Cytometry Analysis Component	SSO	Sequence Specific Oligonucleotides
Fst	Fixation Index	SSP	Sequence Specific Primers
GETS	Government Emergency Telecommunications Service	SSOP	Sequence Specific Oligonucleotide Probes
GCSF	Granulocyte-Colony Stimulating Factor (also	STAR®	Search, Tracking and Registry

	known as filgrastim)		
GIS	Geographic Information System	TC	Transplant Center
GS	General Services	TED	Transplant Essential Data
GTR	Genetic Testing Registry	TNC	Total Nucleated Cell
GvHD	Graft vs Host Disease	TSA	Transportation Security Agency
HCS	HealthCare Standard	UCSF	University of California – San Francisco
HCT	Hematopoietic Cell Transplantation	UI	User Interface
HEPP	Hospital Emergency Preparedness Program	UML	Unified Modeling Language
HHQ	Health History Questionnaire	URD	Unrelated Donor
HHS	Health and Human Services	WGA	Whole Genome Amplification
HIPAA	Health Insurance Portability and Accountability Act	WMDA	World Marrow Donor Association
HIS	Hispanic	WU	Work-up
HLA	Human Leukocyte Antigen		
HML	Histoimmunogenetics Mark-up Language		